



Attorney Docket No.: 2002082-0001

1614  
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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**


Applicant: Stoll, *et al.* Examiner: Cook, Rebecca  
Serial No.: 10/068,035 Art Unit: 1614  
Filing Date: February 5, 2002  
Title: OMEGA-3 FATTY ACIDS AND OMEGA-3 PHOSPHATIDYLCHOLINE IN THE  
TREATMENT OF BIPOLAR DISORDER

COMMISSIONER FOR PATENTS  
P. O. BOX 1450  
ALEXANDRIA, VA 22313-1450

Sir:

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450, on November 13, 2003.

  
Susan M. Dinsmore

**STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE**  
**UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants respectfully request consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

(Select A, B or C below)

A. ☒ This Information Disclosure Statement has been filed:

(check 1, 2 and/or 3 below)

1. ☐ within three months of the filing date of the above identified U.S. Patent application;
2. ☐ within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International application; and/or

3. ☒ before the mailing date of the first Office Action on the merits in the above-identified application.
4. ☐ before the mailing date of a first Office Action after the filing of a Request for Continued Examination under 37C.F.R. §1.114.

No fee or certification is required.

- B. ☐ This Information Disclosure Statement has been filed more than three months after the filing date of the present application and after the mailing date of this first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311.

(check 1 or 2 below)

1. ☐ The fee of \$240 as set forth in 37 C.F.R. §1.17(p) is enclosed; or
2. ☐ Applicants hereby certify, as specified in 37 C.F.R. §1.97(e), that
- (check a or b below)

- a. ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application not more than three months prior to the filing of this Statement; or
- b. ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement.
- c. ☐ items indicated by an asterisk were identified in a recent review of related files.

- C. ☐ This Information Disclosure Statement has been filed after the mailing date of either a Final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311 and before payment of an Issue Fee.

(check 1, 2, and 3 below)

1. ☐ The Applicant hereby certifies, as specified in 37 C.F.R. §1.97(e), that:  
(check a or b below)
  - a. ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application not more than three months prior to the filing of this Statement.
  - b. ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign Patent Office in a counterpart for this application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Statement.
2. ☐ A Petition requesting consideration of the Information Disclosure Statement is attached.
3. ☐ The Petition Fee of \$130 as set forth in 37 C.F.R. §1.17(i)(1) is enclosed.

## PART II - Information Cited

- A. ☒ The Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.
- B. ☐ The Applicant hereby makes the following additional information of record in the above-identified application:

PART III: Explanation of Non-English Language References and Remarks Concerning Other  
Information Cited

- A. ☐ The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):
- B. ☐ The following are remarks concerning the other information cited:

PART IV: Remarks

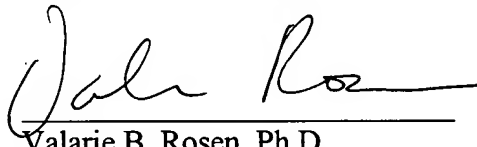
- A.     ☒ Copies of references  
          (check 1 or 2 below)
1.     ☒ A copy of each of the references cited on the attached form PTO-1449  
          (modified) is enclosed;
  2.     ☐ Copies of certain of the references cited on the attached form PTO-1449  
          (modified) are not enclosed because each of these references (indicated by  
          asterisk) was previously cited by or submitted to the Office in a prior  
          application, U.S.S.N.\_\_\_\_\_, which prior application is relied upon for an  
          earlier filing date under 35 U.S.C. § 120.
- B.     ☒ It is respectfully requested that:  
          (check 1, 2, and 3 below)
1.     ☒ The Examiner consider completely the cited information, along with any  
          other information, in reaching a determination concerning the patentability  
          of the present claims;
  2.     ☒ The enclosed form PTO-1449 be signed by the Examiner to evidence that  
          the cited patent(s) and publication(s) has (have) been fully considered by  
          the Patent and Trademark Office during the examination of this  
          application;
  3.     ☒ The citations for the patent(s) and publication(s) be printed on any patent  
          which issues from this application.
- C.     ☒ By submitting this Information Disclosure Statement, Applicants make no  
          representation that a search has been performed, of the extent of any search  
          performed, or that more material information may not exist.
- D.     ☒ By submitting this Information Disclosure Statement, Applicants make no  
          representation that the information cited in the Statement is, or is considered to  
          be, material to patentability as defined in 37 C.F.R. §1.56(b).

- E. ☒ By submitting this Information Disclosure Statement, Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.
- F. ☒ Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

An early and favorable action is hereby requested.

Please charge any additional fees or credit any overpayments to our Deposit Account No. 03-1721.

Respectfully submitted,



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Registration Number 45,698

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(617) 248-5000  
Dated: November 12, 2003



FORM PTO-1449

(REV. 8-83)

U.S. Department of  
Commerce  
Patent and Trademark OfficeATTY. DOCKET:  
2002082-0001IN RE  
APPLICATION  
NO.: 10/068,035

## INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

APPLICANT: Stoll, et al.

FILING DATE:  
February 5, 2002

GROUP: 1614

## U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	4,701,468	Mendy, <i>et al.</i>	October 20, 1987	514	547
	5,252,333	Horrobin	October 12, 1993	424	422
	5,434,183	Larsson-Backström	July 18, 1995	514	549

## U.S. PATENT APPLICATIONS

Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

## FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No
	WO 94/28913	PCT	22 December 1994		
	WO 97/39759	PCT	30 October 1997		
	0 289 204 A2	Europe	02 November 1988		
	0 289 204 A3	Europe	02 November 1988		

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## OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Invitation to Pay Additional Fee with a Communication Relating to the Results of the Partial International Search for PCT/US03/05926
	Adams, J., "Literature Review of Essential Fatty Acids", <i>puterakembara.org</i> , retrieved on July 23, 2003.
	Cohen, et al., "Lecithin in Mania: A Preliminary Report", <i>Am J Psychiatry</i> 137, 242-243, 1980.
	Cohen, et al., "Lecithin in the Treatment of Mania: Double-Blind Placebo-Controlled Trials", <i>Am J Psychiatry</i> 139, 1162-1164, 1982.
	Dimmitt, S.B., "Recent Insights into Dietary Fats and Cardiovascular Disease", <i>Clin. Exp. Pharmacol. Physiol.</i> 22, 204-8, 1995 (abstract only)
	Locke, et al., "Omega-3 Fatty Acids in Major Depression", <i>World Review of Nutrition and Dietetics</i> , 89: 173-185, 2001.



FORM PTO-1449

(REV. 8-83)

U.S. Department of  
Commerce  
Patent and Trademark OfficeATTY. DOCKET:  
2002082-0001IN RE  
APPLICATION  
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(Use several sheets if necessary)

APPLICANT: Stoll, et al.

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GROUP: 1614

Maidment, I., "Are Fish Oils an Effective Therapy in Mental Illness - an Analysis of the Data", *Acta Psychiatr Scand.*, **102**: 3-11, 2000.

Mischoulon, et al., "Docosahexanoic Acid and  $\omega$ -3 Fatty Acids in Depression", *The Psychiatric Clinics of North America*, **23**(4): 785-794, 2000.

Puri, et., "The Effects of Olive Oil on  $\omega$ 3 Fatty Acids and Mood Disorders", *Arch Gen Psychiatry* **57**, 2000.

Puri, et al., "Eicosapentaenoic Acid in Treatment-Resistant Depression", *Archives of General Psychiatry*, **59**(1): 91-92, 2002.

Schreier, H., "Mania Responsive to Lecithin in a 13-Year-Old Girl", *Am J Psychiatry* **139**, 108-110, 1982.

Sperling, R., "Dietary Omega-3 Fatty Acids: Effects on Lipid Mediators of Inflammation and Rheumatoid Arthritis", *Rheumatic Disease Clinics of North America* **17**, 373-389, 1991.

Sperling, et al., "Dietary  $\omega$ -3 Polyunsaturated Fatty Acids Inhibit Phosphoinositide Formation and Chemotaxis in Neutrophils", *J. Clin. Invest* **91**, 651-660, 1993.

Stoll, et al., "Choline Ingestion Increases the Resonance of Choline-Containing Compounds in Human Brain: An In Vivo Proton Magnetic Resonance Study", *Society of Biological Psychiatry* **37**, 170-174, 1995.

Stoll, et al., "Omega 3 Fatty Acids in Bipolar Disorder", *Arch Gen. Psychiatry*, **56**: 407-412, 1999.

Stoll, et al., "Omega-3 Fatty Acids and Bipolar Disorder: A Review", *Prostaglandins, Leukotrienes and Essential Fatty Acids*, **60**: 329-337, 1999.

Stoll, et al., "Methodological Considerations in Clinical Studies of  $\omega$ 3 Fatty Acids in Major Depression and Bipolar Disorder", *World Review of Nutrition and Dietetics*, **88**: 58-67, 2001.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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